Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/AU04/001638

International filing date: 24 November 2004 (24.11.2004)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/525,450
Filing date: 25 November 2003 (25.11.2003)

Date of receipt at the International Bureau: 20 December 2004 (20.12.2004)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)

AU04/01638

PA 1254327

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

December 02, 2004

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE UNDER 35 USC 111.

APPLICATION NUMBER: ***60/525,450***
FILING DATE: ***November 25, 2003***

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS

P. SWAIN
Certifying Officer

PTO/SB/16 (08-03)
Approved for use through 7/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Lab I N . EV332776425US

INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Evan Ka-Loke	CHONG	South Strathfield, Australia
Neil Lawrence	ANDERSON	Roseville, Australia

Additional inventors are being named on the _____ separately numbered sheets attached hereto

TITLE OF THE INVENTION (500 characters max)

A MODULAR CATHETER

16235 U.S. PTO 60/525450 112503

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

[x] Customer Number: 25226

OR

[ ] Firm or Individual Name

Address

City		State		Zip	
Country		Telephone		Fax	

ENCLOSED APPLICATION PARTS (*check all that apply*)

[x] Specification *Number of Pages* 7
[x] Drawing(s) *Number of Sheets* 2
[x] Application Data Sheet. See 37 CFR 1.76 (2 pages)
[ ] CD(s), Number
[x] Other (specify): Return postcard

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

[ ] Applicant claims small entity status. See 37 CFR 1.27.
[ ] A check or money order is enclosed to cover the filing fees.
[x] The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 03-1952
[ ] Payment by credit card. Form PTO-2038 is attached.

FILING FEE AMOUNT ($): 160.00

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

[x] No [ ] Yes, the name of the U.S. Government agency and the Government contract number are: _____

[Page 1 of 1]

Respectfully submitted, Date November 25, 2003

SIGNATURE E. Thomas Wheelock

TYPED OR PRINTED NAME E. Thomas Wheelock

REGISTRATION NO. *(if appropriate)* 28,825

TELEPHONE (650) 813-5739

Docket Number: 273403005000

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV332776425US, in an envelope addressed to: MailStop Provisional Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: November 25, 2003 Signature: Tia Zimmerman (Tia B. Zimmerman)

PA-842099

"A MODULAR CATHETER"

FIELD OF THE INVENTION

[0001] This invention relates to a catheter system. More particularly, the invention relates to a modular catheter.

BACKGROUND TO THE INVENTION

[0002] Catheter systems are becoming an increasingly common way of diagnosing and treating abnormal heart conditions, in particular, heart arrhythmias. Such arrhythmias can be treated with drugs or by use of electronic devices such as pacemakers. However, neither of these treatments cures the problem but only alleviates it.

[0003] In contrast, the use of ablative techniques has been shown to cure arrhythmias. Thus, catheters having mapping electrodes and/or ablative electrodes are inserted through the veins of a patient's body so that the distal end of the catheter can be placed accurately in the relevant chamber of the heart. For the treatment of atrial fibrillation, the distal end is placed at the ostium of one or more of the pulmonary veins, in turn, to effect ablation.

[0004] Thus, it will be appreciated that the catheter needs to be in a sterilised condition for use and various catheter systems with steering mechanisms included are known.

[0005] Because of the fact that the catheter system comes into contact with bodily fluids of a patient and with the increasing prevalence of blood-borne diseases, medical regulations require that these catheter systems are one time use systems only. In other words, once the catheter has been used, it must be disposed of in its entirety.

[0006] Certain institutions do re-sterilise the catheters for re-use. However, there is a problem associated with this in that, in re-sterilising the catheter, it may become degraded and not function correctly.

[0007] In addition, the increasing complexity of catheter systems for monitoring or mapping and/or ablation has resulted in these catheter systems becoming more expensive. Thus, it is costly to dispose of such a system after one use only.

SUMMARY OF THE INVENTION

[0008] According to the invention, there is provided a modular catheter which includes:

an elongate tubular member having a proximal end and a distal end with a lumen extending from the proximal end to the distal end and a plurality of electrodes arranged proximate the distal end;

an elongate shape-imparting mechanism removably received within the lumen of the tubular member such that a distal end of the shape-imparting mechanism is substantially in register with the distal end of the tubular member; and

a control device having a proximal end and a distal end, the proximal end of the tubular member and a proximal end of the shape-imparting mechanism being releasably connectable to the distal end of the control device.

[0009] In a preferred form of the invention, the shape-imparting mechanism and the tubular member are releasably connectable to the control device independently of each other.

[0010] The tubular member, carrying the electrodes, may be a disposable element to be used once only and, thereafter, to be disposed of. The tubular member may be manufactured in accordance with the Applicant's manufacturing technique as disclosed in its PCT Publication No. WO 02/32497 entitled "An electrical lead", the contents of which are incorporated herein by reference. The advantage of this manufacturing technique is that an unimpeded lumen is provided with conductors for the electrodes being at least partially embedded in a wall of the tubular member.

[0011] Thus, the shape-imparting mechanism, which in one form of the invention may be a manipulating mechanism, may be a snug fit within the lumen of the tubular member. The manipulating mechanism may comprise a steering mechanism to effect steering of the distal end, or tip, of the tubular member for manipulating the tubular member through the veins of the person's body and accurately to place the tip of the tubular member in position where mapping and/or ablation is to occur.

[0012] The proximal end of the tubular member may carry a connector thereon for connection to a corresponding connector of the control device. The connector may be any suitable electro-mechanical device for effecting releasable electrical connection between the conductors in the tubular member and electrical leads in the control device while still allowing sterilisation of the handle.

[0013] Similarly, a proximal end of the steering mechanism may carry a coupling device for effecting mechanical coupling to a manipulating element of the control device. The manipulating element may be used to effect lateral displacement of the tip of the tubular member via the steering mechanism. The manipulating member may, for example, be in the form of a knurled thumb-wheel or other such similar device.

[0014] It will be appreciated that a proximal end of the control device, which may be in the form of a handle, may include electrical connectors for connection to an ECG machine and/or to a source of ablation energy such as a RF energy source.

[0015] If desired, the modular catheter may include a disposable, covering member, preferably of a plastics material, for the handle. The covering member may cover controls of the handle to inhibit the access of bodily fluids into such controls and further to enhance the hygienic nature of the catheter.

[0016] In another embodiment of the invention, where steering of the distal tip of the catheter is not required, the shape-imparting mechanism may be a stylet which is received in the lumen of the tubular member. The stylet may impart a fixed curve to the tubular member in applications where fixed curved catheters are required.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] An embodiment of the invention is now described by way of example with reference to the accompanying drawings in which:-

[0018] Figure 1 shows a schematic, exploded view of a modular catheter, in accordance with the invention; and

[0019] Figure 2 shows a schematic, sectional end view of part of the modular catheter.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0020] In the drawings, reference numeral 10 generally designates a modular catheter, in accordance with an embodiment of the invention. The catheter 10 comprises an elongate tubular member 12 having a distal end, or tip, 14 and a proximal end 16. As shown more clearly in Figure 2 of the drawings, the tubular member 12 defines a central lumen 18 extending from the proximal end 16 to the distal end 14 of the tubular member 12.

[0021] A plurality of electrodes 20 are arranged at or proximate the tip 14 of the tubular member 12.

[0022] The tubular member 12 has a peripheral wall 22 in which conductors 24 are embedded. Each electrode 20 has a conductor 24 associated with it. Additional conductors 24 may also be embedded in the wall 22 of the tubular member 12 to be used for temperature monitoring. Because the conductors 24 are arranged within the wall 22 of the tubular member 12, the lumen 18 is unimpeded by conductors to the electrodes 20.

[0023] An electrical connector 26 is arranged at the proximal end 16 of the tubular member 12. The conductors 24 are connected to the electrical connector 26. The electrical connector 26 could be any suitable form of electrical connector such as, for example, an electrical plug-type arrangement, a slip-ring type arrangement, or the like.

[0024] The catheter 10 includes a shape-imparting, or manipulating mechanism, in the form of a steering mechanism 28. The steering mechanism 28 comprises a sheath 30 which is dimensioned to be a snug fit in the lumen 18 of the tubular member 12. The sheath 30, in turn, defines a secondary lumen 32 within which steering wires 34 are arranged. The steering wires 34 effect lateral displacement of the tip 14 of the tubular member 12 and control its radius of curvature to effect steering of the catheter 10 through veins of a patient's body and placement of the tip 14 of the tubular member 12 at the desired location in the patient's heart. Thus, a distal end 36 of the sheath 30 lies substantially in register with the tip 14 of the tubular member 12. A coupling member 38 is arranged at a proximal end of the steering mechanism 28. The coupling member 38 couples the steering mechanism 28 releasably to a control device in the form of a handle 40. More particularly, the coupling member 38 couples the steering mechanism 28 to a control member in the form of a knurled thumb-wheel 42, or the like, of the handle 40 to effect lateral displacement of the distal tip 14 of the tubular member 12 via the steering mechanism 28, in use. In this regard it is to be noted that the steering mechanism 28 is releasably connectable to the handle 40 independently of the tubular member 12

[0025] The handle 40 of the catheter has a distal end 44 and a proximal end 46. The distal end 44 of the handle 40 has a complementary connector (not shown) for connecting to the electrical connector 26 of the tubular member 12. Similarly, the distal end 44 of the handle 40 has a complementary coupling member (also not shown) for coupling to the coupling member 38 of the steering mechanism 28.

[0026] In addition, a connector is arranged at the proximal end 46 of the handle 40 for connection to a monitoring mechanism (not shown) as well as a source of ablation energy such as an RF source (also not shown). The connector at the proximal end preferably incorporates a slip ring arrangement, or some similar form of rotation-permitting arrangement, to allow rotation of the handle 40 without rotating the tubular member 12. Instead of having the connector at the proximal end 46 of the handle 40, a patient cable could connect directly to the connector on the tubular member 12 rather than the connector at the end of the handle 46.

[0027] In use, the steering mechanism 28 is inserted into the lumen 18 of the tubular member 12 so that the distal end 36 of the steering mechanism 28 lies substantially in register with the tip 14 of the tubular member 12. The coupling member 38 of the steering mechanism 28 is mechanically, but releasably, coupled to the complementary coupling member at the distal end 44 of the handle 40. The connector 26 is electrically, but releasably, connected to the complementary connector at the distal end 44 of the handle 40. The catheter 10, so formed, is then connected to the monitoring equipment and the source of ablation energy.

[0028] The clinician then inserts the catheter into the patient's body and controls lateral displacement of the tip 14 of the tubular member 12 via the control device 42. Once positioned, the catheter 10 is used for monitoring and/or ablative purposes.

[0029] After use, once the catheter 10 has been removed from the patient's body, the catheter 10 is disassembled by disconnecting the connector 26 from the handle 40 and, similarly, decoupling the coupling member 38 from the handle 40. The tubular member 12, having been in contact with bodily fluids of the patient, is disposed of. The handle 40 and the steering mechanism 28, not having been in contact with any bodily fluids of the patient, is re-usable after sterilisation, if necessary.

[0030] Further to inhibit the likelihood of contamination of the catheter 10 by a patient's bodily fluids, the catheter 10 optionally includes a cover member in the form of a plastics or elastomeric cover 48 which is a snug fit over the handle 40 to inhibit the access of bodily fluids into switch gear of the handle 40.

[0031] It is also to be noted that, in another embodiment of the invention, at least the steering mechanism 28 and, optionally, the handle 40 can be replaced by a stylet (not shown), which may also be disposable, which is received in the lumen 18 of the tubular member 12. The stylet may

have a predetermined curvature imparted thereto. This curvature may, in turn, be imparted to the tubular member 12 to form a fixed curve catheter.

[0032] It is a particular advantage of the invention that a modular catheter 10 is provided. Because only the tubular member 12 is disposable, the cost of such a catheter 10 is significantly lowered as the whole catheter, including its handle and steering mechanism need not be disposed of after a single use. In fact, the handle 40 and the steering mechanism 20 can be re-used an indefinite number of times and the only part which requires replacement for each use is the tubular member 12.

[0033] In addition, the versatility of the system is substantially increased as the clinician can make use of tubular members 12 having different electrode configurations for different applications. Thus, the modular catheter 10 could include a range of tubular members 12 each having different configurations of electrodes 20 for different applications. It will be appreciate that, with this arrangement, the connector 26 with the associated connector 44 of the handle 40 would be a universal-type connector 26 to cater for the different ranges of electrode configurations. For a catheter 10 with a small number of electrodes 20, this would mean some of the pins in the proximal connector would not be used.

[0034] In addition, different steering mechanisms 28 can also be used by replacing one steering mechanism 28 with a steering mechanism 28 having a different characteristic. This, further improves the versatility of the modular catheter 10 of the present invention. For example, a steering mechanism 28 having a distal end 36 which can bend to a first predetermined radius of curvature may be replaced by a second steering mechanism 28 which has a distal end 36 which can be bent to a second, larger or smaller, radius of curvature and/or a different shape curve than that of the first steering mechanism 28.

[0035] Still further, the modular catheter 10 of the present invention may include handles 40 having different types of controls, each handle type 40 being a re-usable handle.

[0036] It is to be emphasised that, because the tubular member 12 is the only part of the catheter 10 which is used only once, the cost of the modular catheter 10 is significantly reduced over the long term as the handle 40 and the steering mechanism 28 are re-useable.

[0037] It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without

departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

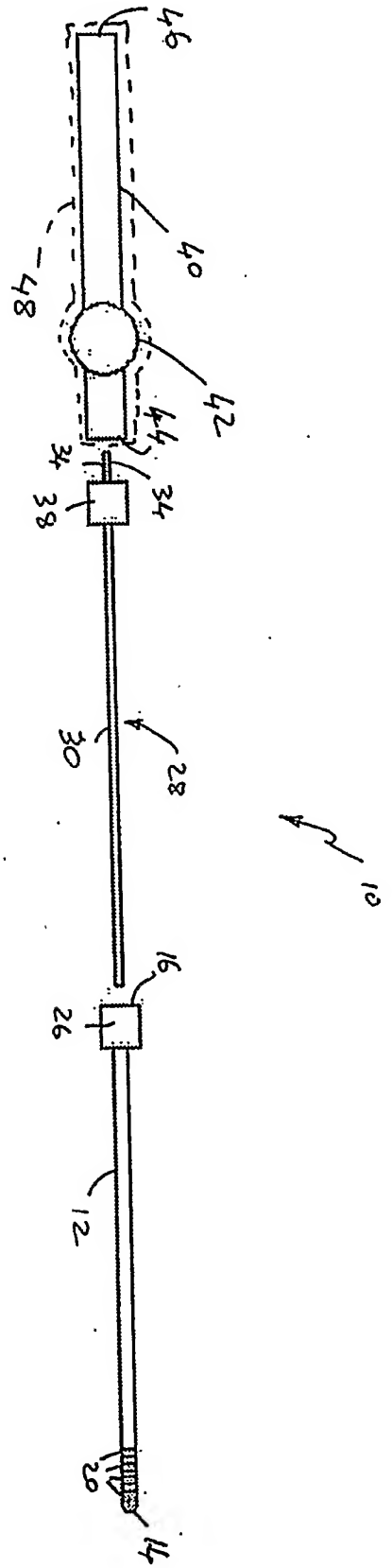

FIG. 1

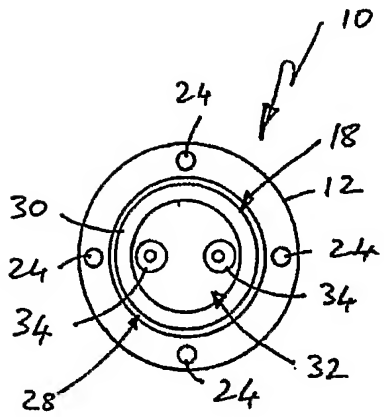

FIG. 2